EPA Comment Number: 550-112

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Please respond to racollette@erols.com

To: Homepage Oppts/DC/USEPA/US@EPA, bcollette@nfi.org, racollete@erols.com

cc:

Subject: Docket No. OPP-00550

Dear Sir or Madam:

We submit the attached comments for Docket No. OPP-00550 regarding the President's Council on Food Safety Strategic Plan for Food Safety.

Thank You.

February 14, 2000

Docket No. OPP-00550

FDA/Dockets Management Branch (HFA-305) 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

RE: The President's Council of Food Safety Strategic Plan,

The National Fisheries Institute (NFI) thanks the President's Council on Food Safety for the opportunity to provide these written comments on the Draft Preliminary Food Safety Strategic Plan. The NFI is the nation's leading trade association representing all aspects of the fish and seafood industry. Its membership covers the following sectors of the industry: harvesters, processors, importers, exporters, distributors, food service operators, retailers, and restaurants. NFI members have long been committed to ensuring that American consumers receive safe and wholesome fish and seafood products.

The following comments are divided into general observations and views about the existing food safety inspection program and the President's Council Strategic Plan and specific comments concerning the individual goals, objectives and actions that are proposed.

General Comments

The NFI welcomes the activities of the President's Council on Food Safety as the appropriate means of building upon our outstanding food safety system here in the United States. U.S. consumers have the safest food in the world at their disposal. It would be

counterproductive to undermine the existing system that provides this comfort and convenience. The NFI recognizes, however, that some aspects of our food safety system are disjointed and fragmented. We welcome the President_s Council Strategic Plan as a means of developing a coordinated and consistent food safety policy for American consumers. The NFI does not support the creation of a single food safety agency for reasons elaborated later on in this letter.

We provide these written comments in the hopes of facilitating the work of the President's Council in developing a rational and effective food safety system that builds upon our proven successes.

We remind the President's Council that the farm is not the only source of food for Americans. The Oceans provide an abundance and diversity of healthful food choices for American consumers. In order for the strategic plan to be truly comprehensive, it should adopt an "Ocean to Table" vision in addition to the "Farm to Table" vision stated in the draft.

As you may know, the NFI has been a pioneer in food safety for over a decade. As far back as 1987, the NFI was pursuing a Hazard Analysis Critical Control Point (HACCP) seafood inspection system. It took years of aggressive leadership by the NFI to finally achieve a HACCP system for seafood ten years later, in 1997. While some food industries have resisted the implementation of mandatory HACCP inspection systems, the NFI embraced the concept as the appropriate next step in this nation's evolving food safety system.

The NFI is therefore deeply committed to maintaining the integrity, objectivity, and effectiveness of the Food and Drug Administration's (FDA) mandatory HACCP program. The NFI, in partnership with the FDA and others, helped initiate the Seafood HACCP Alliance to train the seafood industry in HACCP principles. The NFI, as part of the Alliance, helped create a three-day basic HACCP course for seafood processors and an ENCORE training program to raise the inspection compliance rate and improve overall industry performance. In addition, a one-day sanitation course will soon be introduced. The NFI has also held and participated in several HACCP workshops for seafood importers to ensure the development of adequate importer HACCP verification procedures.

Our commitment to HACCP has led the NFI to oppose an ongoing Administration proposal to transfer the voluntary seafood inspection program of the National Marine Fisheries Service (NMFS) to the FDA. Although it contains food safety elements, the NMFS Voluntary Seafood Inspection Service, authorized by the Agricultural Marketing Act of 1946, is not primarily a food safety program. Rather, it is a fee-for-service marketing and promotional program largely designed to assure seafood buyers that product meets certain quality standards. Combining a voluntary fee-for-service

marketing program with a mandatory food safety program would undermine consumer confidence in the objectivity of the mandatory food safety program. The National Academy of Sciences and the Department of Health and Human Services share this concern. Both have recommended against combining a voluntary marketing program with a mandatory food safety program.

We are deeply concerned that a consolidation of food safety programs into a single agency as proposed by some could jeopardize the FDA's mandatory seafood HACCP program through massive disruptions and confusion in the existing inspection system.

Moreover, creating a single food safety agency would not guarantee that seafood programs would be better funded or supported. The NFI agrees with other major food groups such as the Grocery Manufacturer's Association and the National Food Processors

Association that instead of focusing on the creation of single food safety agency, we should be focused on the creation of a uniform food safety policy. To that end, we feel that the President's Council on Food Safety Strategic Plan should be focused on the following principles:

- 1. The food safety system must be based on sound science
- 2. Education in proper food handling should be promoted
- 3. Food safety agencies must be provided adequate resources, which, in turn, must be properly employed
- 4. Federal and state agencies must work cooperatively.
- 5. Interactive dialogue must occur between the FDA and the regulated industry.
- 6. Food safety risks should be scientifically assessed and identified.
- 7. Preventative measures should be the foundation for a effective food safety control program. Facility inspections and end product testing should be used to verify the effectiveness of the system.

Goals, Objectives and Action Steps

1. Risk Assessment Goal

The government must be proactive in determining the type of research necessary to support scientifically sound risk assessments. Given the reality of finite research budgets, the agencies should interact with the food and academic communities and state and local public health authorities to prioritize research funding. Administration funding initiatives should be realistic and reflect this prioritization.

Consistent with Objective 2, the agencies must expand the surveillance system to obtain more complete and accurate illness outbreak information. The current system is improving but must be extended beyond the existing major surveillance sites. Better coordination in the reporting and dissemination of illness data between federal, state and local public health departments is needed.

With respect to Objectives 3 and 4, the risk assessments must utilize the best scientific information available. The need for default assumptions should be minimized and, when necessary must be based on realistic assumptions. Every risk assessment conducted, particularly those relying on default assumptions, should have a reality check component that cross-references data placed into the model against real world observations and data. The

government agencies should conduct risk assessments in a transparent manner and seek input from academia and the food industry.

2. Risk Management Goal

Risk management strategies should focus on food safety risks identified through sound scientific risk assessments. They should not focus on non-food safety adulteration issues. The promulgation of standards should be carefully evaluated against the industry's ability to meet the standard both technically and financially. When standards are established as a risk management step, maximum flexibility must be afforded to industry to allow for multiple approaches to meet the desired goal. Standards, when necessary, should be phased in over a realistic period of time.

The government should be transparent in establishing its risk management policies and should provide opportunity for adequate input from the affected segments of the food industry. Performance standards and control measures established for HACCP systems should be subject to timely re-evaluation to assess their appropriateness. NFI supports objective 6 and believes encouraging voluntary practices is an appropriate alternative to achieve food safety goals when mandatory standards are not feasible or entirely

justifiable. Technological advancements should be facilitated by expedited government review and approval. The introduction of new technologies should be assisted by government sponsored consumer education programs, consistent with Objective 3, that explain the benefits of technological developments such as irradiation and other treatments designed to minimize microbial pathogens.

Objective 4 should be modified to clarify (i.e. narrow) the definition of "high risk " foods. Most fish and seafood are not high risk foods. Food illness data supports this contention. A similar argument can be made for meat, poultry, etc.

NFI supports most of the proposed actions items in Objective 9. FDA is already making compliance visits to foreign trading partners to assess seafood HACCP programs. NFI supports this effort and urges the agency to expand inspections to a greater number of countries and to follow-up with additional inspections when needed. FDA's inspections augment the verification steps already being taken by seafood importers, therefore, it should disseminate the results of the compliance visits to seafood importers to help guide and improve importer procedures.

FDA should put its sister agencies in other countries to work for them by aggressively seeking equivalency agreements for the seafood HACCP inspection system. This will allow the agency to focus on high-risk products from those countries less far along on the food safety continuum.

Port of entry inspection is reactive and can not be expected to prevent all unsafe food from entering the country. For the seafood industry, port of entry inspection should be used as an additional step for verifying compliance with HACCP requirements rather than as the primary step in assuring food safety. FDA can improve imported seafood safety best by assuring compliance with HACCP requirements. NFI also believes that FDA should provide technical assistance to foreign trading partners to improve their understanding of and compliance with U.S. food safety

standards and requirements.

3. Risk Communication

The roles of various agencies in communicating risks should be defined and agreed on prior to developing food safety communication messages. FDA should maintain the lead communication role for seafood. The agencies should communicate the results of risk assessments with the affected segments of the food industry and actively seek input from them prior to developing communication messages. The appropriateness and impacts of risk communication messages must be carefully weighed before they are issued.

To summarize, NFI believes government efforts to improve food safety in the U.S. should focus on the creation of a uniform food safety policy instead of a single food safety agency. Toward that end, we support overall the President's Council on Food Safety Strategic Plan, although various elements of the Plan need further refinement. With refinement the Plan should help to improve a food safety system that is already one of the best in the world.

Sincerely,

Robert L. Collette V.P.